

<p>FORM PTO-1449</p> <p>INFORMATION DISCLOSURE STATEMENT</p>	<p>ATTY. DOCKET NO. 1611.0510002/AGR</p>	<p>APPLICATION NO. To be assigned 808 261 (Cont. of 08/154,403)</p>
<p>APPLICANTS Mesens et al.</p>		
<p>FILING DATE Herewith</p>		<p>GROUP 1201 To be assigned</p>

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
JKM	AA1	3,773,919	11/1973	Boswell et al.	424	19	
JKM	AB1	4,342,870	08/1982	Kennis et al.	544	282	
JKM	AC1	4,389,330	06/1983	Tice et al.	427	213.36	
JKM	AD1	4,458,076	07/1984	Strupczewski	546	199	
JKM	AE1	4,804,663	02/1989	Kennis et al.	514	258	
JKM	AF1	4,883,666	11/1989	Sabel et al.	424	922	
JKM	AG1	4,940,588	07/1990	Sparks et al.	424	490	
JKM	AH1	4,994,281	02/1991	Muranishi et al.	424	497	
JKM	AI1	5,008,114	04/1991	Lovrecich	424	484	
JKM	AJ1	5,158,952	10/1992	Janssen et al.	514	258	
JKM	AK1	5,407,609	04/1995	Tice et al.	264	46	

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
JKM	AL1	0 368 388	05/1990	Europe			Yes No
JKM	AM1	WO 90/13361	11/1990	WIPO			Yes No
JKM	AN1	WO 94/25460	11/1994	WIPO			Yes No
JKM	AO1	WO 95/13799	05/1995	WIPO			Yes No
	AP1						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

JKM	AR	1	Megens, A.A.H.P. et al., "Comparative Pharmacology of Risperidone, Its Major Metabolite R 76 477 ^(*) and the Corresponding Enantiomers R 78 543 ^(*) and R 78 544 ^(*) in Rats and Dogs", Janssen Research Foundation, Beerse Belgium, N74694, <i>Preclinical Research Report R 64 766/23</i> (June 1990).
JKM	AS	1	Megens, A.A.H.P., et al., "In Vivo Pharmacological Profile of 9-Hydroxyrisperidone, the Major Metabolite of the Novel Antipsychotic Risperidone: Comparison With Risperidone and Haloperidol", Janssen Research Foundation, Beerse, Belgium, N 96295, <i>Preclinical Research Report R 64 766/R 76 477</i> (May 1993).
JKM	AT	1	Suzuki, K., et al., "Microencapsulation and Dissolution Properties of a Neuroleptic in a Biodegradable Polymer, Poly(d,l-lactide)", <i>Journal of Pharmaceutical Sciences</i> , Vol. 74, No. 1, 21-24 (January 1985).

EXAMINER Joseph K. McKane	DATE CONSIDERED 10/14/97
<p>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.</p>	

FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
1611.0510002/AGRAPPLICATION NO.
To be assigned 88241
(Cont. of 08/454,463)APPLICANTS
Mesens et al.FILING DATE
HerewithGROUP 1201
~~To be assigned~~

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
JKM	AA2	5,453,425	09/1995	François et al.	514	258	
JKM	AB2	5,478,564	12/1995	Wantier et al.	514	258	
	AC2						
	AD2						
	AE2						
	AF2						
	AG2						
	AH2						
	AI2						
	AJ2						
	AK2						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2						Yes No
	AM2						Yes No
	AN2						Yes No
	AO2						Yes No
	AP2						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

JKM	AR	2	Ramtools, Z., et al., "Release Kinetics of Fluphenazine from Biodegradable Microspheres", <i>Journal of Microencapsulation</i> , Vol. 8, No. 4, 415-423 (1992).
JKM	AS	2	Chang, R., et al., "Dissolution Characteristics of Polycaprolactone-Polylactide Microspheres of Chlorpromazine", <i>Drug Development and Industrial Pharmacy</i> , Vol. 12, No. 14, 2355-2380 (1986).
JKM	AT	2	Maulding, H.V., et al., "Biodegradable Microcapsules: Acceleration of Polymeric Excipient Hydrolytic Rate By Incorporation of a Basic Medicament", <i>Journal of Controlled Release</i> , 3: 103-117 (1986).

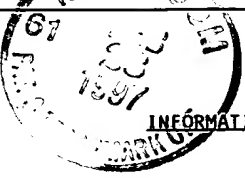
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10/14/97

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 <p>FORM PTO-1449</p> <p>INFORMATION DISCLOSURE STATEMENT</p>	ATTY. DOCKET NO. 1611.0510002/AGR	APPLICATION NO. To be assigned <u>808 261</u> (Cont. of 08/454,403)
	APPLICANTS Mesens et al.	
	FILING DATE Herewith	GROUP <u>1201</u> To be assigned

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3						
	AB3						
	AC3						
	AD3						
	AE3						
	AF3						
	AG3						
	AH3						
	AI3						
	AJ3						
	AK3						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3						Yes No
	AM3						Yes No
	AN3						Yes No
	AO3						Yes No
	AP3						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

JKm	AR	3	Leysen, J.E., et al., "Biochemical Profile of Risperidone, a New Antipsychotic", <i>The Journal of Pharmacology and Experimental Therapeutics</i> , Vol. 247, No. 2, 661-670 (1988).
JKm	AS	3	Janssen, P.A.J., et al., "Pharmacology of Risperidone (R 64 766), a New Antipsychotic With Serotonin - S ₂ and Dopamine - D ₂ Antagonistic Properties", <i>The Journal of Pharmacology and Experimental Therapeutics</i> , Vol. 244, No. 2, 685-693 (1988).
JKm	AT	3	Chouinard, G., et al., "A Canadian Multicenter Placebo-Controlled Study of Fixed Doses of Risperidone and Haloperidol in the Treatment of Chronic Schizophrenic Patients", <i>Journal of Clinical Psychopharmacology</i> , Vol. 13, No. 1, 25-40 (1993).

EXAMINER <u>Joseph K. McKane</u>	DATE CONSIDERED <u>10/14/97</u>
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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
1611.0510002APPLICATION NO.
08/808,261APPLICANTS
Mesens et al.FILING DATE
February 28, 1997GROUP 1201
~~Is to be assigned~~

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA2						
	AB2						
	AC2	3,197,180	07/1965	Bates et al.	514	258	
	AD2	3,523,906	08/1970	Vrancken et al.	424	490	
	AE2	3,691,090	09/1972	Kitajima et al.	424	426	
	AF2	3,737,337	06/1973	Schnoring et al.	544	282	
	AG2	3,891,570	06/1975	Fukushima et al.	514	258	
	AH2	3,923,288	12/1975	King et al.	427	213	
	AI2	3,960,757	06/1976	Morishita et al.	424	497	
	AJ2	4,034,965	07/1977	King et al.	424	1.25	
	AK2	4,111,402	09/1978	Barbini et al.	424	1.33	

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1						Yes No
	AM1						Yes No
	AN1						Yes No
	AO1						Yes No
JKM	AP1	EP 0 052 510	05/1982	Europe			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

JKM	AR	4	Baker, J.R., "Motionless Mixers Stir Up New Uses", <i>Chemical Engineering Progress</i> :32-38 (June 1991)
JKM	AS	4	Borison, R.L. et al., "Clinical Overview of Risperidone", in: Meltzer, H., Y., ed., <i>Novel Antipsychotic Drugs</i> , Raven Press, Ltd., N.Y.: 233-239 (1992)
JKM	AT	4	Chemineer, "Kenics Static Mixers", <i>Bulletin 800</i> :1-11 (1986)

EXAMINER

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10/14/97

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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 1611.0510002	APPLICATION NO. 08/808,261
	APPLICANTS Mesens et al.	
	FILING DATE February 28, 1997	GROUP 1207 To be assigned

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
Jkm	AA3	4,128,641	12/1978	Itil et al.	424	490	
Jkm	AB3	4,201,482	05/1980	Imhäuser et al.	424	19	
Jkm	AC3	4,208,136	06/1980	King et al.	424	497	
Jkm	AD3	4,329,331	05/1982	Kallick et al.	514	258	
Jkm	AE3	4,335,127	06/1982	Vandenberk et al.	427	213	
Jkm	AF3	4,337,261	06/1982	Shutske et al.	424	490	
Jkm	AG3	4,352,811	10/1982	Strupczewski	514	258	
Jkm	AH3	4,443,451	04/1984	Kennis et al.	424	422	
Jkm	AI3	4,485,107	11/1984	Kennis et al.	424	484	
Jkm	AJ3	4,489,055	12/1984	Couvreux et al.	427	213.36	
Jkm	AK3	4,511,258	04/1985	Federighi et al.	544	282	

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
Jkm	AL2	EP 0 071 454	02/1983	Europe			Yes No
Jkm	AM2	EP 0 129 619	01/1985	Europe			Yes No
Jkm	AN2	EP 0 195 450	09/1986	Europe			Yes No
Jkm	AO2	EP 0 248 531	12/1987	Europe			Yes No
Jkm	AP2	EP 0 266 119	05/1988	Europe			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

Jkm	AR	5	Glazer, W.M. et al., "Depot Neuroleptic Therapy: An Underutilized Treatment Option", <i>J. Clin. Psychiatry</i> 53 (12):426-433 (December, 1992)
Jkm	AS	5	Heinrich, K. et al., "Experimental Comparison of the Efficacy and Compatibility of Risperidone and Clozapine in Acute Schizophrenia", in: Kane, J.M. (ed), <i>Risperidone: Major Progress in Antipsychotic Treatment. Oxford Clinical Communications, Oxford:37-39 (1991)</i>
Jkm	AT	5	Photocopy of an unofficial English Translation of Japanese Patent Application No. Hei-04 (1992)-332441, "Sustained-Release Microsphere and Process for Producing the Same," filed by Yoshitomi Pharmaceutical Industries, Ltd., which is the priority document of PCT Application No. 94/10982, pp. 1-12

EXAMINER Joseph K. McKane	DATE CONSIDERED 10/14/97
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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 1611.0510002	APPLICATION NO. 08/808,261
	APPLICANTS Mesens et al.	
	FILING DATE February 28, 1997	GROUP 120 To be assigned

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
JKM	AA4	4,529,727	07/1985	Kennis et al.	424	422	
JKM	AB4	4,530,840	07/1985	Tice et al.	424	488	
JKM	AC4	4,542,025	09/1985	Tice et al.	424	487	
JKM	AD4	4,585,482	04/1986	Tice et al.	424	469	
JKM	AE4	4,614,440	09/1986	King et al.	424	441	
JKM	AF4	4,616,937	10/1986	King et al.	424	440	
JKM	AG4	4,643,584	02/1987	Allocca et al.	514	258	
JKM	AH4	4,665,075	03/1987	Vandenberk et al.	546	199	
JKM	AI4	4,675,189	06/1987	Kent et al.	427	213.36	
JKM	AJ4	4,677,191	06/1987	Tankana et al.	514	258	
JKM	AK4	4,683,288	07/1987	Tankana et al.	424	488	

FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
JKM	AL3	WO 88/01165	02/1988	PCT	—	—	Yes No
JKM	AM3	WO 91/13595	09/1991	PCT	—	—	Yes No
JKM	AN3	WO 91/17772	11/1991	PCT	—	—	Yes No
JKM	AO3	1 212 730	11/1970	United Kingdom	—	—	Yes No
JKM	AP3	1 351 811	03/1974	United Kingdom	—	—	Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
JKM	AR	6	Janssen and Niemegeers, "Chemistry and pharmacology of compounds related to 4-(4-hydroxy-4-phenyl-piperidino)-butyrophenone", <i>Arzneim.-Forsch. (Drug Res.)</i> 12:765-767 (1959)
JKM	AS	6	Janssen, P.A.J. et al., "Is it Possible to Predict the Clinical Effects of Neuroleptic Drugs (Major Tranquilizers) from Animal Data?", <i>Arzneimitt. Forsch. (Drug Res.)</i> 10:1196-1206 (1965)
JKM	AT	6	Koch Engineering Company Inc., "Static Mixing Technology", Article:1-15 (1991)

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	APPLICANTS Mesens et al.	
	FILING DATE February 28, 1997	GROUP 1201 To be assigned

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
JKM	AA5	4,689,330	08/1987	Janssen et al.	424	490	
JKM	AB5	4,696,258	09/1987	Magrath et al.	424	48	
JKM	AC5	4,731,205	03/1988	McNulty et al.	424	494	
JKM	AD5	4,737,500	04/1988	Sorg et al.	424	497	
JKM	AE5	4,753,535	06/1988	King et al.	424	469	
JKM	AF5	4,765,204	08/1988	Buchholz et al.	424	464	
JKM	AG5	4,793,713	12/1988	King et al.	424	497	
JKM	AH5	4,798,786	01/1989	Tice et al.	424	484	
JKM	AI5	4,808,007	02/1989	King et al.	424	422	
JKM	AJ5	4,835,139	05/1989	Tice et al.	424	19	
JKM	AK5	4,897,268	01/1990	Tice et al.	424	19	

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
JKM	AL4	2 015 360	09/1979	United Kingdom			Yes No
JKM	AM4	2 120 113	11/1983	United Kingdom			Yes No
JKM	AN4	0 196 132	10/1986	Europe			Yes No
JKM	AO4	2 246 573	02/1992	United Kingdom			Yes No
JKM	AP4	0 486 959	05/1992	Europe			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	Z	Koch Engineering Company Inc., "All Mixing Problems Are Not Alike", 1 page, Product Brochure
AS	Z	Koflo Corporation, "Static In-Line Mixers", 4 pages, Product Brochure
AT	Z	Komax Systems Inc., "Triple Action Static Mixers", 2 pages, Product Brochure

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	APPLICANTS Mesens et al.	
	FILING DATE February 28, 1997	GROUP <u>1201</u> 10-808,261

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
JKm	AA6	4,936,689	06/1990	Federighi et al.	424	469	
JKm	AB6	5,075,109	12/1991	Tice et al.	424	19	
JKm	AC6	5,102,872	04/1992	Singh et al.	424	489	
	AD6						
	AE6						
	AF6						
	AG6						
	AH6						
	AI6						
	AJ6						
	AK6						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
JKm	AL5	WO 94/10982	07/1994	WIPO			Yes No
	AM5						Yes No
	AN5						Yes No
	AO5						Yes No
	AP5						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

JKm	AR	8	Leysen, J.E. et al., "In vitro receptor binding and neurotransmitter uptake inhibition profile of R 64 766, R 76 477, R 78 543 and R 78 544", Janssen Research Foundation, Beerse, Belgium, N 79120, Preclinical Research Report R 64 766/28, 11 pages (January 1991)
JKm	AS	8	Mertens, C., "Long-term treatment of chronic schizophrenic patients with risperidone", in: Kane, J.M. (ed), Risperidone: Major Progress in Antipsychotic Treatment, Oxford Clinical Communications, Oxford:44-48 (1991)
JKm	AT	8	Mutsakis et al., "Advances In Static Mixing Technology", Chemical Engineering Progress:42-48 (July 1986)

EXAMINER <u>Joseph K. McKane</u>	DATE CONSIDERED <u>10/14/97</u>
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	APPLICANTS Mesens et al.	
	FILING DATE February 28, 1997	GROUP <u>1201</u> To be assigned

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
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FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
JKM	AR	2	Niemegeers and Janssen, "A Systematic Study of the Pharmacological Activities of Dopamine Antagonists", in: <i>Life Science</i> 24(24) :2201-2216, Pergamon Press Ltd (1979)
JKM	AS	2	Niemegeers et al., "Antiemetic Specificity of Dopamine Antagonists", <i>Psychopharmacology</i> 78:210-213 (1982)
JKM	AT	2	Streiff, F., "In-line Dispersion and Mass Transfer using Static Mixing Equipment", <i>Sulzer Technical Review</i> 3:108-114 (1977)

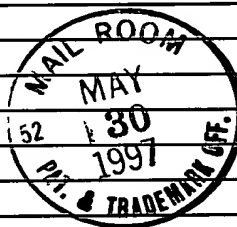
EXAMINER <u>Joseph K. McKane</u>	DATE CONSIDERED <u>10/14/97</u>
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	APPLICANTS Mesens et al.	
	FILING DATE February 28, 1997	GROUP 1201 Technical

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						



FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	10	Abstract of WO 94/10982, Kino et al., "Sustained-release Microspheres Requiring No Surgical Implant - Contains Hydrophobic Antipsychotic Encapsulated in Biodegradable Polymer, Allowing Prolonged Therapeutic Effect by Infrequent Administration"
	AS	10	
	AT	10	

EXAMINER Joseph K. McKane	DATE CONSIDERED 10/14/97
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